

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS)	
LIABILITY LITIGATION)	MDL No. 1:13-md-2419-FDS
)	
This Document Relates to:)	Judge Rya W. Zobel
)	
All Cases)	(Leave to File Granted on June 24, 2015)
)	

**DEFENDANT AMERIDOSE LLC'S REPLY IN SUPPORT OF ITS MOTION FOR
PROTECTIVE ORDER AND MOTION TO QUASH THE DEPOSITION NOTICE TO
AMERIDOSE LLC**

I. INTRODUCTION

The Saint Thomas Entities' ("STEs") Opposition to Ameridose LLC's Motion for Protective Order and Motion to Quash Deposition Notice runs afoul of the Federal Rules of Civil Procedure and Tennessee law. *First*, the STEs' Opposition asks this Court to ignore the "consent" provision contained in F.R.C.P. 30(b)(6) and require Ameridose to "prepare someone to testify." (STEs' Opposition, NECC MDL Docket No. 1943 at 6.) As mentioned in its Motion for Protective Order and Motion to Quash Deposition Notice, however, there is no "other person" presently associated with Ameridose who will consent to testify. (Ameridose's Motion, NECC MDL Docket. No. 1879-1 at 4.) The STEs cannot contravene the plain language of F.R.C.P. 30(b)(6) simply because it is more convenient for them.

Second, the STEs' Opposition concedes that its discovery requests are not supported by products liability standards, yet asks this Court to premise discovery under a novel negligence

theory without any foundation. The theory is that Ameridose somehow had a duty to supervise NECC or otherwise maintain the cleanroom where NECC allegedly compounded contaminated MPA *three years after* Ameridose vacated the premises it shared with NECC. (STEs' Opposition, NECC MDL Docket No. 1943 at 3-4.) Unsurprisingly, this novel theory of liability is not supported by Tennessee law because Ameridose, as a **separate entity from NECC**, cannot be held liable for NECC's actions (under any theory of liability), and common ownership is not enough for the STEs to overcome the presumption of separateness recognized under both Massachusetts and Tennessee law. Moreover, the fact that Ameridose shared premises with NECC until 2009 does not rise to a duty of supervision.

For these reasons, and for all of the reasons included in Ameridose's Motion for Protective Order and Motion to Quash Deposition Notice, this Court should quash the deposition notice served on Ameridose and forbid the STEs from taking the deposition of an Ameridose witness.

II. ARGUMENT

A. The STEs cannot compel Ameridose to designate a representative who will not consent to testify under Federal Rule of Civil Procedure 30(b)(6).

Apparently recognizing that Ameridose's owners, managers, and/or agents cannot not be compelled to testify because of their Fifth Amendment privilege, the STEs argue that "Ameridose has an obligation to prepare someone [such as a consultant] to testify."¹ (STEs'

¹ The STEs assert that "if [Ameridose's owners, managers, and/or agents] have Fifth Amendment concerns, then, by definition, they must have been intimately involved with NECC's operations." (STEs' Opposition, NECC MDL Docket No. 1943 at 10.) This argument is without merit for the reasons more fully detailed in this Reply Memorandum, including the fact that Ameridose and NECC are separate and distinct companies and Ameridose did not compound or dispense the MPA at issue. However, because NECC and Ameridose have some common owners, and because that group of individuals (except for Lisa Cadden) has been criminally charged, Ameridose's owners and/or managers' right to invoke the protections offered by the Fifth Amendment are valid, without the suggested implication that Ameridose was involved in and/or responsible for compounding the contaminated MPA at issue. In

Opposition, NECC MDL Docket No. 1943 at 6, 8.) This argument fails for three reasons. First, Ameridose, as a corporate entity, cannot prepare someone to testify without the assistance of its owners, managers, and/or agents, all of whom have Fifth Amendment concerns. (Ameridose’s Motion, NECC MDL Docket No. 1879-1 at 5.) Second, any “other person” who Ameridose could arguably designate (e.g. its former employees) will not consent to testify as a 30(b)(6) witness. (*Id.* at 4.) Third, the STEs’ argument wholly ignores the practical reality that Ameridose has not been operating for over two years and does not have the financial ability to pay consultants to study reams of documents and testify about them.

The STEs rely on *Briddell v. Saint Gobain Abrasives Inc.* to support the proposition that a “corporation must prepare and educate the designee so he or she ‘can answer fully, completely, [and] unequivocally.’” (STEs’ Opposition, NECC MDL Docket No. 1943 at 6 (citing *Briddell v. Saint Gobain Abrasives, Inc.*, 233 F.R.D. 57, 60 (D. Mass. 2005).) But *Briddell* is distinguishable from the circumstances presented here. In *Briddell*, the defendant argued that its designated 30(b)(6) witness did not have personal knowledge of certain information requested by the plaintiff. As such, the defendant argued, its designated witness should not have been required to testify about matters beyond his personal knowledge. The court rejected this argument, noting that the defendant had a duty to prepare the witness and was required to “use documents, past employees, and other resources in performing this required preparation.” *Id.* at 60.

Unlike in *Briddell*, there are no readily or reasonably available “documents, past employees, or other resources” that Ameridose could use to educate and prepare someone to testify and “answer fully, completely, [and] unequivocally.” (*See* Ameridose’s Motion, NECC

short, the STEs improperly attempt to widen whatever inference to which they may be entitled, an inference that will ultimately be determined later by either Judge Zobel or a trial court in Tennessee.

MDL Docket No. 1879-1 at 4-5, 10.) Importantly, *Briddell* did not involve a company such as Ameridose that had not been operating for over two (2) years and lacked the financial ability to compensate consultants for the time needed to become educated so they could become a corporate designee. *Briddell* also did not involve a situation in which the defendant corporation did not have any current or former employees who were willing to consent to be a 30(b)(6) witness. Nor did the designated 30(b)(6) witness in *Briddell* have Fifth Amendment concerns like Ameridose's owners, managers, and/or agents. These significant differences buttress Ameridose's position that this litigation presents a series of unique facts that prevent Ameridose from designating a 30(b)(6) witness: Ameridose has not been operating for over two years; it does not have the financial ability to compensate consultants for the time needed to become educated enough to be a corporate designee; its owners, managers, and/or agents have legitimate Fifth Amendment rights; and no current, or former employees will consent to testify under F.R.C.P. 30(b)(6). Thus, *Briddell*'s discussion about preparing an already designated 30(b)(6) witness is inapposite here.²

B. The STEs cannot prove that Ameridose is liable under common law negligence principles.

In their Opposition, the STEs concede that Ameridose cannot be held liable under Tennessee's Product Liability Act because it did not manufacture or sell MPA. While this should end any inquiry regarding Ameridose's alleged negligence, the STEs argue that they "are seeking to hold Ameridose responsible under a negligence-based theory: that Ameridose's negligent acts

² The STEs state that Ameridose "cites no case holding that a corporation should be relieved of its obligation to testify in these circumstances." (STEs' Opposition, NECC MDL Docket No. 1943 at 6; *see also* 8.) To be clear, Ameridose does not argue that *it* has a Fifth Amendment privilege. Rather, Ameridose's owners, managers, and/or agents have indicated that they will all exercise their legitimate rights under the Fifth Amendment. But quite obviously, Ameridose cannot fulfill its obligation to prepare a 30(b)(6) witness without an individual willing to waive his or her Fifth Amendment rights by consenting to testify.

and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs” because of its “central role in the design of NECC’s facility.” (STEs’ Opposition, NECC MDL Docket No. 1943 at 3-4.) Thus, the STEs argue, they are entitled to discovery “to prove that Ameridose was negligent in its role as NECC’s distribution center and in its participation in the design and management of the cleanrooms in which the contaminated MPA was later compounded.” (*Id.* at 3.)³

Although the STEs do not specifically allege what “negligent acts or omissions” of Ameridose’s “led to the contamination of MPA,” their novel attempt to impose liability on Ameridose under a common law negligence theory must fail because (1) Ameridose did not owe the Plaintiffs a duty to supervise NECC or maintain the NECC cleanroom and (2) the STEs cannot prove that Ameridose’s conduct was the proximate cause of the MPA contamination, meningitis outbreak, or resulting injuries.

1. Ameridose cannot be held liable because it did not owe a duty to the Plaintiffs in this litigation.

The STEs should not be entitled to discovery from Ameridose because Ameridose – a separate entity from NECC – did not owe a duty to the Plaintiffs in this litigation. While the STEs abandoned their argument that Ameridose should be held liable under Tennessee’s Product Liability Act, they now argue that Ameridose “owed a duty to the Plaintiffs in this litigation and breached it.” (STEs’ Opposition, NECC MDL Docket No. 1943 at 4). It is axiomatic under

³ In its discovery responses, Ameridose answered that it did not manufacture, sell, or distribute MPA. Throughout this litigation, there has been no evidence to the contrary, even in the many depositions of the STEs’ and Tennessee Clinic’s employees. The STEs’ reliance on a document filed with the Massachusetts Board of Registration in Pharmacy in May 2012 is completely misplaced because that document was filed in an effort to open at another building, to operate in a different way than Ameridose had previously operated. (STEs’ Opposition, NECC MDL Docket No. 1943 at 3.) Those future plans never came into fruition. Therefore, the STEs’ argument is insufficient to open the expensive and thorny gates of discovery here.

Tennessee law that a defendant cannot be held liable under a common law negligence theory unless it owed a plaintiff a duty of care. *See McClenahan v. Cooley*, 806 S.W.2d 767, 774 (Tenn. 1991). Despite this widely accepted principle, the STEs presumably intend to prove that Ameridose somehow had a duty to supervise NECC or somehow prevent NECC from making and selling contaminated MPA *three years after* Ameridose vacated the facility where NECC later allegedly compounded contaminated MPA.

The STEs' novel attempt to impose a duty on Ameridose – a separate entity from NECC – is not supported by Tennessee law, even if Tennessee law were to apply (which Ameridose does not concede). It is beyond logic for the STEs to argue that Ameridose had a duty to supervise NECC or somehow prevent NECC from making and selling contaminated MPA under circumstances in which: Ameridose operated a **separate** facility during the period in which MPA was allegedly contaminated; Ameridose did not compound, manufacture or sell MPA; the STEs did not buy the product at issue; the Tennessee Clinic Defendants, the supposed agent of the STEs, was not an Ameridose customer; and the STEs did not rely upon anything from or about Ameridose regarding the product at issue or NECC's capabilities. The STEs could have attached depositions or affidavits from STEs' employees about the degree to which the STEs relied upon Ameridose for anything regarding MPA or NECC's overall quality or regulatory compliance. They did not. Certainly, if Ameridose did not owe a duty to the Plaintiffs, then it cannot be held liable under a common law theory of negligence. Consequently, the STEs would not be entitled to discovery from Ameridose since their comparative fault claim would necessarily fail.

Moreover, as a separate entity from NECC, Ameridose is entitled to a presumption of separateness under both Massachusetts and Tennessee law. *See, e.g., Scott v. NG U.S. 1, Inc.*,

881 N.E.2d 1125, 1131 (Ma. 2008); *Hiller Cranberry Prods., Inc. v. Koplovsky, Inc.*, 165 F.3d 1, 10 (1st Cir. 1999); *Continental Bankers Life Ins. Co. of the South v. Bank of Alamo*, 578 S.W.2d 625, 631-32 (Tenn. 1979); *Edmunds v. Delta Partners, L.L.C.*, 403 S.W.2d 812, 828 (Tenn. Ct. App. 2012). This means that the STEs cannot rely solely on common ownership as a means to impose liability on Ameridose for NECC's conduct, or to craft some duty that otherwise does not exist. This also means that the STEs cannot base their entire theory of liability solely on the fact that Ameridose once occupied the same facility where NECC allegedly compounded contaminated MPA. Indeed, the only way that the STEs can overcome this presumption of separateness is by proving that Ameridose is liable under an alter ego theory, which the STEs have already, in this very litigation, strenuously argued and recognized is a high burden under Tennessee law, and a rare exception to the general rule of separateness. (See NECC MDL Docket No. 894 at 10-14.) As separate entities, Ameridose and NECC are each responsible only for their own negligence.⁴ *McIntyre v. Balentine*, 833 S.W.2d 52, 58 (Tenn. 1992). And even if the STEs could somehow prove that Ameridose is liable under an alter ego theory, Ameridose would be lumped together with NECC on a verdict form, further undermining the STEs' request for discovery from Ameridose.

2. Ameridose cannot be held liable because the STEs cannot establish that Ameridose's conduct was the proximate cause of the MPA contamination, meningitis outbreak, or resulting injuries.

The STEs also have to establish that Ameridose's conduct (separate from its role as a manufacturer and seller of products) was the proximate cause of the MPA contamination,

⁴ The STEs misquote Ameridose by stating that "Ameridose's argument that it would be 'legally impossible' for a jury to find it was negligent is simply without basis." (STEs' Opposition, NECC MDL Docket No. 1943 at 9.) Ameridose said that since it did not "manufacture, test, compound, dispense, or sell the MPA at issue, it would be legally impossible to find Ameridose at fault **and NECC not at fault.**" (Ameridose's Motion, NECC MDL Docket No. 1879-1 at 13) (emphasis added).) The difference is significant.

meningitis outbreak, or resulting injuries. Considering the STEs never purchased or injected MPA and considering there is no evidence that the STEs somehow relied on Ameridose for any information about NECC or its products, the STEs cannot prove that Ameridose's conduct proximately caused the MPA contamination, meningitis outbreak, or resulting injuries.

In their Opposition, the STEs go to great lengths to argue that they are entitled to discovery regarding Ameridose's involvement with the cleanroom it occupied from 2006-2009, which NECC then took over in 2009 until the meningitis outbreak in 2012. Interestingly, the STEs appear to argue that Ameridose's involvement with the NECC cleanroom *three years before* the meningitis outbreak in 2012 was the proximate cause of the MPA contamination, meningitis outbreak, or resulting injuries.⁵ Aside from the fact that Ameridose did not owe a legal duty to the Plaintiffs, the STEs have failed to connect the dots to show how discovery from Ameridose regarding its involvement *three years before* the meningitis outbreak in 2012 somehow proves that Ameridose's conduct proximately caused the MPA contamination, meningitis outbreak, or resulting injuries. This is especially important considering there were likely hundreds of other drugs and batches manufactured by Ameridose before 2009, and hundreds more compounded by NECC after 2009, yet only *one* drug (and *three* batches) were allegedly contaminated.

To prove that Ameridose's involvement with the cleanroom proximately caused the MPA contamination, meningitis outbreak, or resulting injuries, the STEs would need an expert to testify that: Ameridose was a substantial factor in the design of the NECC cleanroom; the NECC

⁵ The STEs consistently refer to the cleanroom as the "NECC cleanroom." (See, e.g., STEs' Opposition, NECC MDL Docket No. 1943 at 4.) When the cleanroom was designed and built in 2006, it was an Ameridose cleanroom that Ameridose used for products it manufactured. In 2009, NECC allegedly took over the cleanroom for products it later compounded. Ameridose did not have any involvement with the cleanroom after 2009, a fact mentioned in response to written discovery.

cleanroom was defective; the NECC cleanroom harbored bacteria for years; and suddenly, six years later, the bacteria blossomed into an outbreak of *one* drug, and only *three* batches of that drug. It is hard to imagine that any expert witness would testify that a company absent from the premises for three years was a proximate cause of a fungal contamination in 2012. Surely, if Ford Motors vacated a manufacturing facility that Chrysler later occupied, and Chrysler later manufactured defective vehicles, would Ford have a duty to ensure that Chrysler did not manufacture defective vehicles simply because it formerly occupied the facility? Of course not, and the same is true here.

Finally, if any discovery is permitted as to the status and condition of the cleanrooms in 2009 or before, it should start with NECC. The STEs can depose NECC's owners in their capacity as NECC witnesses; they do not need to depose Ameridose witnesses to discover this information, especially considering Ameridose did not make or sell the product at issue.

III. CONCLUSION

The STEs' Opposition to Ameridose's Motion for Protective Order and Motion to Quash Deposition Notice falls short of showing why they are entitled to discovery from Ameridose. Not only do they completely ignore the Federal Rules of Civil Procedure, but they concede that Ameridose cannot be held liable under Tennessee's Product Liability Act (despite arguing that it should be held liable under a novel common law theory of negligence). Under the facts of this litigation, this concession ends any inquiry as to Ameridose's alleged negligence. Accordingly, Ameridose respectfully requests that this Court issue an Order quashing the deposition notice served on Ameridose LLC and forbidding the STEs from taking the deposition of Ameridose LLC.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 25, 2015, a copy of the foregoing **Defendant Ameridose LLC's Reply in Support of its Motion for Protective Order and Motion to Quash the Deposition Notice to Ameridose LLC** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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